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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/475,548 | 12/30/1999 | JEFFREY STEWARD | M-7891-US | 6479 |

7590

10/19/2005

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EXAMINER

THANH, LOAN H

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/475,548

Applicant(s)

STEWART ET AL.

Examiner

LoAn H. Thanh

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3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-7,11-13,17-19 and 21-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-7,11-13,17-19,21-33 and 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 April 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>12/20/01</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

The drawings submitted 04/13/05 have been accepted in view of the amendment and is considered the formal drawings by the Examiner.

The amendment to the specification submitted 04/13/05 have been accepted and obviated the specification objection.

The IDS filed 12/20/01 has been considered and is in the record history of the application. Attached is a copy of the IDS that was considered on 02/13/02.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,3-5,7,11-13,17-18,21-22, 25-33 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Briskin et al. (USPN 5,735,811).

Briskin et al. disclose a medical assembly comprising a catheter having a distal and proximal end; a delivery lumen 106 ; a first transducer (110/112, 142/144, 206/208, 244/246) having anchoring points. Specifically figure 10 will be discussed with anchoring points at 248 and at 250 and 252. Anchoring points are also disclosed at the flanges between two transducers. The gap is clearly shown between the inner surface of the transducer 244/246 and the outer surface of the catheter. Briskin et al. disclose

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drugs in col.6 lines 40-61, electrical signal with frequency between 10-300 kHz and voltage between 10-200 V. With respect to the limitation of the low density material contained in the gap, it is the Examiner's position that it is inherent that the gap contains a low density material such as ambient air in absence of the prior art's disclosure of the device being in a vacuum environment. For example in a syringe device, there is air in the syringe, but the disclosure for the most part will not disclose that there is air in the syringe.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 19,23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brisken et al. (USPN 5,735,811) in view of Bock (USPN 5,618,275).

Brisken et al. disclose the invention as substantially claimed. See Brisken et al. above. However, Brisken et al. does not disclose adjusting the ultrasonic energy by manipulating an electronic signal applied to the transducer. Bock discloses an ultrasonic device, which delivers agents to the target tissue with a power source which is adjustable for generating low and high frequency electric signals to the transducer. It would have been obvious to one of ordinary skill in the art to modify the device of Brisken et al. with an ultrasonic power supply for adjusting the electronic signal to

control the ultrasonic energy in order to provide differences in energy applied depending on the requirement of penetration depth to allow the agent to penetrate the tissue.

Response to Arguments

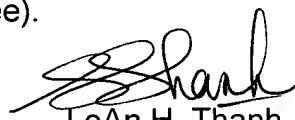
Applicant's arguments with respect to claims 1,3-5,7,11-13,17-33 have been considered but are not considered persuasive. Applicant is referred to figure 10 of the Briskin et al. 5,735,811 patent. Applicant argues that there is no disclosure that the region is fluid tight. The drawings are part of the disclosure of the application. Briskin et al. shows the transducer is clearly sealed to the anchor points and as such would inherently have a low density material contained in the gap. Without any further structural distinguishing features, the prior art anticipates the claims. With respect to arguments directed at claims 12 and 25, there are a plurality of transducers and there is a distance between the at least 2 transducers to allow the catheter to bend in the area between the pair of the adjacent transducers. The prior art shows the structure that applicant has claimed and the intended use of applicants claim can be met by the prior art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H. Thanh whose telephone number is (571) 272-4966. The examiner can normally be reached on Mon. - Fri. (First Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


LoAn H. Thanh
Primary Examiner
Art Unit 3763

LT
10/17/05